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510(k) Summary

OCT 26 2012

A. Submitter Information

Quantum Dental Technologies Inc.
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Date Prepared: Tuesday, October 09, 2012

B. Device Identification:

Classification Name	Laser fluorescence caries detection device
Proprietary Name	The Canary System
Device Classification	Class II
Panel	Dental
Device Product Code	NBL
Previous FDA Status	The Canary System has no prior FDA Status
Basis for Submission	New Device

C. Identification of Predicate Device:

Device	Applicant	510(k) No.	Date Cleared
DIAGNOdent	KAVO DIAGNODENT	K983658	February 22, 2000
SOPRO Life	SOPRO	K092583	January 13, 2010

D. Device Description:

The Canary System™ uses a low powered 660 nm wavelength laser to examine the tooth surface. When this laser light is shone on the tooth the laser light is scattered and absorbed. An absorbed portion of the light is converted into heat and emits thermal infrared (Photothermal Radiometry, PTR) and another part of the light excites the tissue and emits optically converted light (Luminescence; LUM), which shows the difference between what appears to be healthy tooth structure and areas suspected of being carious tooth structure. Compared to a healthy tooth, areas suspected of being carious or possibly having other defects such as micro cracks absorb more light and generate higher PTR signals and lower LUM signals. The Canary System is very safe because the temperature rise on the tooth surface by the laser is only 1 - 2°C, which is much lower temperature than hot beverages.

Modulated laser light hitting the tooth surface generates a thermal diffusion (heat transfer) wave. The depth that this wave can penetrate is determined by the modulation frequency. Even though its sensitivity is lower than PTR, modulated light scattering also gives information from deep inside the enamel by luminescence. The Canary System can detect suspect areas, up to a depth

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of 5mm because The Canary System uses a 2Hz frequency modulation that penetrates deeper than higher frequencies (100s or 1000s Hz) and the detected PTR/LUM signals deliver integrated information from the surface to the penetration depth.

The measured PTR and LUM signals are combined into a Canary Number. As the suspicion of a carious lesion develops, the Canary Number increases. With remineralization treatment, or lesion reduction in size, the Canary Number appears to decrease.

The Canary System is associated with a photographic image of the tooth surface being examined. The images are displayed on an accompanying monitor for immediate chair-side review with the patient. Images are also shown in Canary Reports incorporating Canary Numbers and color codes for the examined teeth. The Canary software is able to record and store the Canary Numbers, images of the surfaces examined, along with the dentist's treatment recommendation.

E. Intended Use:

The Canary System is intended to be used by qualified dental professionals as an aid in the detection and monitoring of dental caries, and as an intra-oral camera to record anatomical details.

F. Indications for use:

The Canary System is indicated as an aid in the detection and monitoring of dental caries and as an intraoral camera to visualize and record anatomical details.

G. Substantial Equivalence:

Safety and effectiveness comparison to predicate devices:

COMPARISON OF THE ABILITY TO DETECT AREAS OF SUSPICION BY TOOTH SURFACE

CRITERIA	The Canary System	DIAGNODent	SOPRO
Examination of Interproximal Caries Areas	YES	NO	NO
Examination of Pit and Fissure Caries	YES	YES	YES
Smooth Surface Caries	YES	YES	YES
Evaluation of Possible Caries Around Visible Margins of Restorations	YES	NO	NO
Evaliation of Possible Subsurface Caries lesions	YES	NO	NO

COMPARISON BY FUNCTIONALITY

CRITERIA	The Canary System	DIAGNODent	SOPRO
Necessary	Removal of pools of	Clean tooth using any	Clean tooth using any

pre-treatment of teeth	saliva using air drying or dabbing with cotton	method and dry	method
Detection of areas of suspect Incipient	YES	YES	YES
Target Population	Dentist's Offices	Dentist's Offices	Dentist's Offices
Printed / Electronic Report for patients and providers	YES	NO	YES
Visual Image	YES	NO	YES

TECHNICAL SPECIFICATIONS

CRITERIA	The Canary System	DIAGNODent	SOPRO
Indications for use	An aid in the detection and monitoring of dental caries and as an intraoral camera to visualize and record anatomical details	Aid in the diagnosis of dental caries	Intended to be used by qualified physicians in dentistry as an aid in the diagnosis of dental caries, and as an intraoral camera to visualize anatomical details invisible to the naked eye or with a mirror.
Core Technology	Combined Photothermal radiometry (PTR) and modulated luminescence (LUM) caries detection device	Fluorescence caries detection device	Light-induced fluorescence caries detection device
How suspicion of caries are detected	The Canary System shines a 2 Hz pulsed laser light (660nm) on the tooth surface and the device collects the converted and emitted infrared radiation (2-5µm) by heat released from the tooth (1-2 deg. C maximum increase in heat) and luminescence (715-800nm) when the laser modulates. By the interaction of the laser light with the crystalline structure of the enamel and dentin, the emitted luminescence and thermal infrared signal provide information about the health of the tooth and areas that might be suspected of having dental caries .	DIAGNOdent emits red laser light at a wavelength of 655 nm onto a tooth surface. This wavelength causes porphyrins (coloured protein molecules) in carious tissue to fluoresce, resulting in elevated scale readings on the display of the system. The presence of bacterial by-products is an indirect measure that caries are present.	SOPROLIFE emits blue LED (wavelength of 450 nm) onto a tooth surface. This wavelength excites the dentin, which, in response, reflects a light signal called fluorescence. The colour of the fluorescence signal is green when the dentin is healthy and dark red, when the dentin is infected.
How suspicion of caries are reported	The Canary Number is a combination of the PTR and LUM amplitude and	Scale of 1 – 100 with readings below 13 suggests a healthy	Colour suggests health of dentin. Red suggests caries in the dentin. Green

	phase readings at a point on a tooth surface. The Canary Number scale is from 0 – 100. Canary Numbers below 20 suggest a healthy tooth surface. Canary Numbers above 70 suggest the possible presence of advanced decay. Canary Numbers between 21 – 70 suggests the presence of an early lesion or decay and treatment depends upon location of these suspect areas and patient risk factors.	tooth surface. Readings over 20 suggest presence of caries into the dentin. Readings over 30 suggest the presence of caries into dentin requiring restoration.	suggests healthy dentin. The stronger the red colour the larger the suspicious area of caries.

CRITERIA	The Canary System	DIAGNODent	SOPRO
Probe	Lenses and mirrors	Fiber Optic	Fiber Optic
Light source	660 nm <50 mW Laser, sinusoidally modulated at 2Hz	655 nm <1 mw Laser	450 nm LED
Camera	CMOS Resolution: 640 x 480 pixels	N/A	¼" CCD; Resolution (752x582) PAL; (768x494) NTSC
Returned light	AC or modulated Luminescence + thermal infrared Pulsing the laser light allow for measurement of both the luminescence and changes in thermal properties.	Fluorescence (DC luminescence)	Fluorescence (DC luminescence)
Detectors for Returned Light	• Photodiode for LUM and or AC Fluorescence • Mid-IR detector for PTR • Visible Range CMOS Camera to track area scanned & visual surface changes	Photodiode for DC fluorescence	Visible range CMOS camera for DC fluorescence
Sterilization and Disinfection	Disposable, one-time use plastic sleeve and plastic tip. The Canary System unit and cables can also be disinfected with alcohol-based solutions.	Probe tip only, autoclave	Probe autoclave
Medical Device Classification	II	II	II
User interface	• Graphical, numeric and audible tones.	Numeric and audible tones LED numbers	Image with colours

	• Visual image of surface under examination and surface that was examined previously • Reports generated for patients.		
Patient & Dentist Reports	Reports generated for patients and dentists which can be printed or stored on The Canary for later review	No printed reports	Reports stored on dental practice software where bridging is available
Power source	100-120/200-240, 50/60Hz	6- AA Alkaline battery	115-230V, 50-60Hz

The Canary System is substantially equivalent to other legally marketed devices in the United States. This conclusion is based on indications for use, bench, *in vitro* studies, as well as EMC, laser and electrical safety testing. Differences that exist between The Canary System and the predicate devices relating to technical operation and performance do not affect the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 26 2012

Quantum Dental Technologies, Incorporated
Josh Silvertown, Ph.D, M.B.A.
Vice President, Corporate Development
748 Briar Hill Avenue
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Canada M6B 1L3

Re: K112139
Trade/Device Name: The Canary System™
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: II
Product Code: NBL
Dated: October 9, 2012
Received: October 10, 2012

Dear Dr. Silvertown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112139

Device Name: The Canary System™

Indications for Use:
The Canary System is intended to be used by qualified dental professionals as an aid in the diagnosis of dental caries, and as an intra-oral camera to visualize and record anatomical details.

Prescription Use X AND/OR Over-the-counter Use NO
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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